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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,300	06/27/2003	Kenneth William Cale	77008	8052

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EXAMINER

MAHAFKEY, KELLY J

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,300

Applicant(s)

CALE ET AL.

Examiner

Kelly Mahafkey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/24/03 1/30/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 3, 8, 14, and 15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3, 8, 14, and 15 of copending Application No. 10/912870. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-7, 9-13, and 16-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/912870. Although the conflicting claims are not identical, they are not patentably distinct from each other because '870 does not recite exactly the same range of the present application, however, '870 does encompass the entire range of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high quality" in claims 1 and 10 is a relative term that renders the claim indefinite. The term "high quality" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

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reasonably apprised of the scope of the invention. It is unclear to the examiner what "quality" is, how quality is determined, and further, how "high" quality is determined.

The term "minimally processed" in claims 1 and 10 is a relative term that renders the claim indefinite. The term "minimally processed" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to what type of process the limitation is referring to and to what degree minimally encompasses.

The term "daily value" in claims 1, 7-10, 18-20 is a relative term that renders the claim indefinite. The term "daily value" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to the amount of material that "daily value" encompasses. The examiner notes that a daily value is different for an infant, a child, a man, an athlete, a woman, an elderly person, and a sickly person. It is further noted that within each category, different authorities have established different guidelines for asserting daily recommended values and that these guidelines change over time.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Villagran et al. (US 2002/0037353 A1).

Villagran et al. (Villagran) teaches of fortified beverages with improved texture and flavor impact. Villagran teaches that the composition includes creamers such as whole milk

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solids, a soluble beverage component such as milk, sweetener, and 0.1-5% vitamins and minerals (0022-0024, 0045, 0046, 0050, 0054, and 0058). In example 10, Villagran teaches that the composition can contain over 10 vitamins and minerals (a fortification component) in an amount that is more than 20% of the daily-recommended value, water, 4.5% sweetener, 2.2% protein (contained in the 2% milk, Simplesse 100®, and the Non Fat Dry Milk), and 1% fat (contained in the 2% skim milk). In Example 10, Villagran teaches that the ratio of dairy fat to total fat is 1 and that the ratio of milk protein to total protein is 7.5 or about 8. The following information was utilized for the compositional percentage calculations: As evidenced by the National Dairy Council, 2% milk contains 2% fat or 5g of fat per serving (Milk Handout) and about 3.25% protein or about 8g of protein per cup of milk (Nutrient Content of Select Dairy Foods). As evidenced by the National Dairy Council (Newer Knowledge of Dairy Food: Milk) all milks have a similar nutrient content, thus the dried milk powder would also contain about 3.25% protein or about 8g of protein per cup of dried milk. The protein content stated to be contained in dried milk powder is further supported by the University of Nebraska and the United States Department of Agriculture, which establish a non-fat dried milk that contains 34% protein (Non-Fat Dry Milk in Drought Diets). As evidenced by Simplesse®, Simplesse® 100 contains 54% protein.

The composition of example 10 includes the following fat and protein products:

- 50% 2% Milk
 - 2% of the milk is fat
 - thus the composition includes $50\% \times (0.02) = 1\%$ milk fat
 - 3.25% of the milk is protein

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- thus the composition includes $50\% \times (0.0325) = 1.625\%$ milk protein
- 1% Simplese 100 ®
 - 54% of Simplese 100 ® is protein
 - thus the composition includes $1\% \times (0.54) = 0.54\%$ whey protein
- 0.56% Non Fat Dry Milk
 - 3.25% of the milk is protein
 - thus the composition includes $0.56\% \times (0.0325) = 0.0182\%$ milk protein

Thus the composition includes a total of 1% fat and about 2.19% protein. The first and second ratios were calculated as specified by applicant. The first ratio of milk protein to total protein was 0.75 or about .8 ($1.65/2.19$). The second ratio of milk fat to total fat was 1 (1/1).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The National Dairy Council (Functional Foods: An Overview) teaches that dairy foods, such as milk, are important functional food specifically because they have components, such as proteins and fats, which provide health-enhancing effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly Mahafkey whose telephone number is (571) 272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 4/11/06

Kelly Mahafkey
Examiner
Art Unit 1761


KEITH HENDRICKS
PRIMARY EXAMINER